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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,842	07/26/2005	Gallus Schechner	P2107-267	8538
2352 7590 04/20/2009 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403				
EXAMINER				
DEES, NIKKI H				
ART UNIT		PAPER NUMBER		
1794				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,842

Applicant(s)

SCHECHNER ET AL.

Examiner

Nikki H. Dees

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009 and 17 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-35 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-35 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2009, has been entered.
2. Claims 1, 3-5, 7-35, and 37-42 are currently pending in the Application. Claims 2, 6, and 36 have been cancelled.

Claim Objections

3. Claim 7 is objected to because of the following informalities: delete the extra ".". Appropriate correction is required.
4. Claims 21, 22, 25-28, 30, 31, 33, 35, and 42 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

5. Claim 1 has been amended to require a coating material comprising a composite of a calcium salt and a protein. Claims 21, 22, 25-28, 30, 31, 35, and 42 are to a composite, a calcium salt, or a combination thereof and are not considered to be further limiting of the claim to a composite.
6. Claim 1 has also been amended to limit the calcium salt in the composite. Claim 33 limits the calcium salts to the same compounds as claim 1 and is therefore not considered to be further limiting.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Claim 24 claims "further aids" for inclusion in the chewing gum. It is unclear what compounds Applicant intends to encompass by claiming "further aids."

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 3-5, 7-35 and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kropf et al. (DE 10063945 A1) in view of Greenberg et al. (5,980,955).
12. Kropf et al. teach a dental adhesive film comprising a poorly soluble calcium salt [0009]. The slightly water soluble calcium salts are preferably salts of hydroxyapatite or fluoroapatite [0015]. The calcium salts are preferably from 10-300 nm in size, and are in the form of rod-shaped crystals [0015]. The film produced comprises about 1% of the composite material of the invention [0089]. The calcium salt is preferably provided in combination with a protein. Proteins may include casein, collagen, albumin and gelatin [0019], [0026]. The proteins may also function as surface-modification agents by adsorbing to the nanoparticles of calcium and preventing agglomeration of the particles [0018].
13. Kropf et al. go on to teach sweeteners for use in their invention including sucrose, lactose, fructose [0054]. They also teach intense sweeteners such as aspartame, thaumatin and sodium cyclamate [0054], inclusion of which would result in a substantially sugar-free product.
14. The invention of Kropf et al. may further comprise fluorine compounds such as sodium fluoride or tin fluoride [0047]. The invention may also comprise flavors and other fillers [0049]-[0055].

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15. Kropf et al. teach chewing gums as another means of introducing active ingredients to tooth and gum surfaces [0003].
16. Kropf et al. are silent as to the composition of the particular coating layers of the chewing gum. They are also silent as to a method for making a chewing gum product comprising their calcium composite.
17. Greenberg et al. teach a coated chewing gum product wherein the coating contains a poorly water-soluble salt of calcium (Abstract).
18. The coating material of Greenberg et al. may further comprise sweeteners such as dextrose, maltose, erythritol, xylitol, hydrogenated isomaltulose (isomalt) and other polyols alone or in combination. High intensity sweeteners are also taught for use in the invention (col. 5 lines 61-62). Further, there may be layers of different primary coating materials (col. 4 lines 21-32).
19. Greenberg et al. state that each component of the coating may be applied in a single layer, or in a plurality of layers that are the same or different. Preferably, about 30 to 60 layers are applied (col. 7 lines 4-13).
20. Greenberg et al. also teach a method for producing a chewing gum comprising coating a gum core with a coating syrup comprising a slightly water-soluble calcium salt (Abstract). The coating syrup may further comprise sweeteners (col. 5 lines 40-56). The chewing gum core is coated by at least one coating step. Preferably, about 30 to 60 layers are applied (col. 7 lines 4-13). After coating, the core is dried (col. 7 lines 28-36). The gum core may also be coated with a dry powder of sweetener after coating with a liquid syrup (col. 6 lines 63-66). The powder may also comprise calcium

carbonate (col. 7 lines 1-3). The calcium salt is taught in an amount preferably from 1.5 to about 5% in the coating layer (col. 2 lines 64-67).

21. As Kropf teaches the composite of a protein and nanoparticle calcium salt for the remineralization of tooth enamel, as well of the use chewing gums to expose remineralizing agents to teeth, one of ordinary skill would have found it obvious to include the remineralizing agents of Kropf in traditional chewing gum compositions, as taught by Greenberg, in order to result in a chewing gum product containing nanoparticle-sized calcium in a form that has significant residence time in the mouth in order to improve the dental hygiene of the user, or mineralize the enamel or dentine of the user in the presence of the calcium particles.

Response to Arguments

22. Applicant's arguments filed January 30, 2009, have been fully considered but they are not persuasive.

23. Applicant argues (Remarks, pp. 10-11) Kropf is directed to dental films, while the Applicant's invention is a coating material for chewing gum.

24. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

25. Kropf is used to teach a composite of a slightly water-soluble calcium salt and a protein component, with the salts and proteins of Kropf being the same as claimed by Applicants. Further, the particle size and the shape of the calcium salt as claimed by Applicants are the same as taught by Kropf. The composition of Kropf is used for remineralization of dentin.

26. Kropf further teaches that chewing gums may be used to administer agents to the surface of the tooth as they generally have a long residence time in the mouth [0002]. Kropf is not being used to teach the method of making the film. Therefore, Applicant's arguments that the dental film is made by a different method than the chewing gum claimed are not relevant to the rejection presented.

27. Applicant argues that one of ordinary skill would not have found it obvious to include calcium composites having lower solubility in the invention of Greenberg (Remarks, pp. 12-13).

28. The rejection of the claims has been modified as is detailed *supra*. Kropf et al. is used to teach the calcium composite as is required by Applicant's claims. Kropf et al. also teach the presence of remineralizing agents in chewing gums, therefore providing the artisan motivation to utilize traditional chewing gum materials, as taught by Greenberg et al. for the production of a chewing gum comprising a remineralizing calcium component.

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29. Applicant argues that the differences in solubility between the calcium salts of the Kropf reference and the calcium salts of the Greenberg reference would preclude the combination of the references (Remarks, p. 12).

30. Again, the rejection of the claims has been modified as is detailed *supra*. Kropf et al. is used to teach the calcium composite as is required by Applicant's claims. Kropf et al. also teach the presence of remineralizing agents in chewing gums, therefore providing the artisan motivation to utilize traditional chewing gum materials, as taught by Greenberg et al. for the production of a chewing gum comprising a remineralizing calcium component.

31. Applicant argues that the prior art is against the use of protein compositions (Remarks, p. 13).

32. It is unclear to what prior art applicant is referring. It is known to include remineralizing agents for teeth in chewing gums, as is taught by Kropf.

33. In this case, Kropf is used to teach the nanoparticles of calcium for use in the invention. It appears that Applicants are using the same slightly water-soluble calcium salts as taught by Kropf. Greenberg teaches a method for making a chewing gum comprising a coating using conventional chewing gum materials. One of ordinary skill desiring not only to provide calcium to the surface of the tooth would have recognized chewing gums to be an obvious way to do so, and further would have recognized that including the agent to be delivered in the coating of the chewing gum is an obvious method for delivery.

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34. The desirability of including the calcium composite of Kropf into a chewing gum coating is supported by the teachings of Kropf, as has been detailed *supra*. One of ordinary skill would have found it obvious to try the combination of Kropf and Greenberg based on these teachings.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nikki H. Dees/
Examiner, Art Unit 1794
/Lien T Tran/
Primary Examiner, Art Unit 1794

Nikki H. Dees
Examiner
Art Unit 1794